

## **Assembly Bill No. 2648**

### **CHAPTER 93**

An act to amend Sections 12811.5 and 12836.6 of the Food and Agricultural Code, relating to pesticides.

[Approved by Governor July 20, 2006. Filed with  
Secretary of State July 20, 2006.]

#### **LEGISLATIVE COUNSEL'S DIGEST**

AB 2648, Matthews. Pesticides.

Existing law authorizes the Director of the Department of Pesticide Regulation to rely upon any evaluations of previously submitted data with respect to an application for registration, an amendment to a registration, or to maintain a registration of a registered pesticide if certain criteria are met including that the applicant either obtain written permission from the owner to rely on the data or irrevocably offer to pay the owner a share of the cost of producing the data, as specified.

This bill would make technical-clarifying amendments to those provisions.

*The people of the State of California do enact as follows:*

**SECTION 1.** Section 12811.5 of the Food and Agricultural Code is amended to read:

12811.5. The director may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to the registration of a registered pesticide product, or to maintain the registration of a registered pesticide product regardless of the ownership of the data previously evaluated. However, effective January 1, 2006, applicants will be subject to the following provisions:

(a) If an applicant for registration of a pesticide product, or an amendment to the registration of a registered pesticide product, including a registrant that desires to maintain its registration of a registered pesticide product after the director makes a formal reevaluation request for additional data, does not submit its own data to fulfill a current data requirement imposed by the director and relies upon data that the applicant does not own or have written permission to rely upon that was submitted to the director by another entity after January 1, 1991, and meets the three criteria set forth in this subdivision, the applicant must either (i) obtain written permission from the data owner to rely on the data, (ii) formulate or obtain its product from a source that has data authorization from the

data owner, or a source that complies with subdivision (c), or (iii) if the data meets the criteria set forth in paragraphs (1), (2), and (3), irrevocably offer to pay the data owner a share of the cost of producing the data and comply with the provisions of subdivision (d). The director may rely upon data submitted prior to January 1, 1991, or that does not meet the criteria set forth in paragraphs (1), (2), and (3) to support any application or comply with any formal reevaluation request for additional data, without permission from the data owner. An offer to pay, and a payment pursuant to that offer, shall only be required as to data not submitted by the applicant that meets the criteria set forth in paragraphs (1), (2), and (3). To be eligible for cost sharing pursuant to this subdivision, the data must meet all of the following requirements:

(1) The data was required by the director in order to obtain, amend, or maintain the data owner's California registration or registrations for uses covered by the application, amendment, or formal reevaluation request for additional data.

(2) There has been no arbitration award, data compensation, or data cost-sharing agreement pertaining to data supporting the product at the federal level pursuant to Section 3(c)(1) (F)(iii) or 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136a(c)(1)(F)(iii) or 136a(c)(2)(B)), or, if an award or agreement exists, the use of data in California was excluded from compensation or cost sharing on its face.

(3) The data that fulfills a current requirement was submitted to the United States Environmental Protection Agency or the department no more than 15 years prior to the date of the applicant's California registration, application, or amendment or the formal reevaluation request for additional data to which the registrant's reliance responds, provided that as to data submitted to the department as of August 1, 2005, in support of the first registration of a product, the applicable period shall be 17 years from the date of submission to the United States Environmental Protection Agency.

(b) If the director previously imposed a specific documented data requirement after January 1, 1991, to obtain, amend, or maintain the California registration of a pesticide product substantially similar to the applicant's product and that data requirement is not currently imposed in California for registration, amendment, or maintenance of the applicant's product, the applicant is further obligated to submit data to meet the requirement, obtain written permission from an owner of the data to rely upon the data, formulate or obtain its product from a source that has authorization from the data owner to rely upon the data or from a source that complies with subdivision (c), or, if the data meets the criteria set forth in paragraphs (1), (2), and (3), irrevocably offer to pay the data owner a share in the cost of producing the data and comply with the provisions of subdivision (c). An offer to pay, and a payment pursuant to that offer, shall only be required as to data not submitted by the applicant that meets the criteria set forth in paragraphs (1), (2), and (3). To be

eligible for cost sharing pursuant to this subdivision, the data must meet all of the following requirements:

(1) The data met a specific, documented requirement of the director to obtain, amend, or maintain the California registration of the data owner's pesticide product for a use covered by the applicant's application or amendment.

(2) There has been no arbitration award, data compensation, or data cost-sharing agreement pertaining to data supporting the product at the federal level pursuant to Section 3(c)(1)(F)(iii) or 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136a(c)(1)(F)(iii) or 136a(c)(2)(B)), or, if an award or agreement exists, the use of the data in California was excluded from compensation or cost sharing on its face.

(3) The data was submitted to the U.S. Environmental Protection Agency or Department of Pesticide Regulation by the data owner after January 1, 1991, and no more than 15 years prior to the date of the applicant's California application for registration or amendment or the response to a formal specific document data requirement to which the registrant's reliance responds, provided that as to data submitted to the department as of August 1, 2005, in support of the first registration of a product, the applicable period shall be 17 years from the date of submission to the U.S. Environmental Protection Agency.

(c) An applicant may formulate its product from a source that does not have data authorization provided that source has submitted data to support the product or makes or has made an irrevocable offer to pay the data owner a share of the cost of producing the data required pursuant to subdivision (a) or (b) for the applicant's product and complies with or has made payment in accordance with the provisions of subdivision (d). In the event that the source has already reached a data compensation or cost-sharing agreement or there has been an arbitration award under the Federal Insecticide, Fungicide, and Rodenticide Act (commencing at 7 U.S.C. Sec. 136) that excludes the right to rely on the data to satisfy the California requirement on its face, the source must make or have made a new irrevocable offer to pay a share of the cost of producing that data to support the applicant's product in California and comply with the provisions of subdivision (d).

(d) If an applicant is required to offer to pay a share in the cost of producing the data pursuant to subdivision (a) or (b), or if a source of product makes an offer pursuant to subdivision (c), the applicant or source must submit to the data owner upon application to the department an irrevocable offer to pay the data owner a share in the cost of producing the data and to comply with regulations promulgated under this subdivision to determine the amount and terms, if the parties cannot agree. If a data owner for which cost sharing is required under subdivision (a) or (b) cannot be identified from information readily available to the applicant, the applicant's obligation under subdivision (a) or (b) will be absolved if the data owner does not identify himself or herself to the applicant within

12 months after registration of the pesticide product. If within 12 months of registration, the data owner identifies himself or herself to the applicant and the applicant has not already made an irrevocable offer to pay to the data owner, or the applicant's source of product has not made an offer pursuant to subdivision (c), the applicant must do so promptly. In either event, the specific terms and amount of payments to be made shall be fixed by agreement between the applicant and the data owner, but determination of those amounts and terms shall not delay approval of the applicant's application.

If agreement cannot be reached about the terms and amount of payment required by this section at any time more than 90 days after issuance of an irrevocable offer to pay, either the applicant, source or data owner may initiate, or with the consent of all parties, join a proceeding under the Federal Insecticide, Fungicide, and Rodenticide Act (commencing at 7 U.S.C. Sec. 136), pursuant to regulations promulgated by the director pursuant to this statute. The purpose of this proceeding shall be to determine the amount due under this section. The director shall promulgate those regulations as emergency regulations within 60 days of the enactment of the bill that enacts this section. The regulations shall provide all of the following:

(1) Allow the proceeding authorized by this subdivision, upon mutual agreement of the parties, to be consolidated with dispute resolution under the Federal Insecticide Fungicide and Rodenticide Act (commencing at 7 U.S.C. Sec. 136).

(2) Require that the decisionmaker consider, among other factors, that the data owner's exclusive right to sell the pesticide resulted in the data owner recovering all or part of the costs of generating the data.

(3) Require that the parties to the proceeding share equally in the payment of the expenses thereof.

(e) If a data owner fails to participate in a procedure for reaching an agreement or in a proceeding as required by subdivision (d), or fails to comply with the terms of an agreement or decision conducted under subdivision (d), then that data owner forfeits his or her right to cost recovery as a result of the use of the data at issue.

(f) If the director finds that an applicant has failed to make an offer to pay as required under subdivision (a) or (b), or if its source of product has failed to make an offer pursuant to subdivision (c), or if an applicant or its source of product has failed to participate in a proceeding for reaching an agreement, or has refused to participate in a proceeding pursuant to subdivision (d), or has failed to comply with an agreement or to comply with an order, or to pay an award resulting from that proceeding, the director shall cancel the registration of the pesticide product in support of which the data was used in accordance with the provisions of subdivision (g), notwithstanding the provisions of Section 12825.

(g) If the applicant subject to subdivision (a) or (b) fails to comply with the provisions of this article, the data owner shall notify the director of the specific provision of noncompliance and provide proof of notification to

the applicant of its claim of noncompliance. All parties shall have 30 days from the date of receipt of notification by the director to submit written evidence or arguments to the director regarding the claim and any defenses thereto. The director shall provide a written finding within 60 days of the deadline for submission as to the claim and the resulting consequences.

(h) No hearing or live testimony shall be conducted under subdivision (g) and this proceeding shall not be used as mechanism to prevent or delay the registration or payment for cost sharing as determined by this article. The finding of the director shall be final and conclusive, except that any party aggrieved by such a finding may seek review within 30 days of the finding pursuant to Section 1094.5 of the Code of Civil Procedure.

(i) In lieu of seeking a determination by the director and cancellation of the registration pursuant to subdivision (f), the data owner may bring an action in any California court of competent jurisdiction against the applicant to enforce the obligations of that party set forth in the provisions of this section.

(j) No cost sharing as provided in subdivisions (a), (b), and (c) shall be required to support an application for annual renewal of a pesticide product registration, provided this provision shall not authorize renewal of a product registered prior to the effective date of this section if that registration is declared to have been unlawfully issued by a court of competent jurisdiction.

(k) The Department of Pesticide Regulation shall make available in the public domain its index of data submitted in support of registration applications, the ownership of that data, and the date it was submitted to California.

SEC. 2. Section 12836.6 of the Food and Agricultural Code is amended to read:

12836.6. The director shall, with the assistance of the Legislative Analyst, conduct a study to consider more carefully the consequences of data-sharing agreements required under Section 12811.5 and the volume of high-hazard pesticides sold in California. The report shall be submitted to the Legislature no later than December 31, 2008.